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09

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/460,920	12/14/99	PIPER	B LA0046A

023914
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HM22/0829

EXAMINER

COOK, R

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/460,920

Applicant(s)

Piper

Examiner

Rebecca Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 19, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-72 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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³⁷⁻⁷²
Claims ~~1-36~~ are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 39 and 57 the term “substantially” in the recitation “substantially equivalent efficacy” is relative. Applicant’s argument that it is defined in the specification is not persuasive, since the incidence of adverse events and amount of low dose is not disclosed in the specification.

✓ It is not seen that claims 39 and 68-70 further limit claim ³⁷~~1~~. The specification discloses that the combination reduces side effects, therefore this is inherent in claim ³⁷~~1~~. Applicant can overcome this rejection by amending claim 37 to recite the inherent property of claim 39.

✓ There is no antecedent basis in claim 1 for the recitations in claims 4 and 5 and 6 and 7 “starting daily dosage” and “daily maintenance dosage.”

✓ Claims 41 and 43 do not further limit claims 37, 40 or 42. Claims 43 and 56 do not further limit claims 42 or claim 37. They require a “low dose” of metformin and glyburide. Applicant’s argument that “low dose” can refer to dose of metformin, glyburide or both is not persuasive, since that intent does not mean that one can be the dose normally employed.

✓ In claims 18-20 the terms “where necessary” and “generally accepted medical practice” are confusing as to their parameters. Amending “where necessary” to recite when the dose is increased will overcome this rejection, if there is support in the specification for an amendment.

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Amending "generally accepted medical practice" to recite specific dose or range will overcome this rejection, if there is support in the specification for an amendment

✗ In claims 61 and 62 the term "such" is colloquial.

✓ In claims 57 and 68 the term "and/or" is confusing. In re Anderegg 51 USPQ 66.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Press Release 9/30/99: Bristol-Myers Squibb Files NDA for Novel Oral Antidiabetic Drug (PR) in view of Earle et al.

Applicant's argument that Earle et al does not recite the dosage disclosed in the specification. This is not persuasive, since it is not claimed in the broad claims. Furthermore, "less than 800 mg" includes 799 mg and no substantial difference is seen in 1 mg, or even 50 mg. Moreover, no unobviousness is seen in the particle size and distribution of the metformin and glyburide, since the therapeutic results is the same as the known product.

It is noted that applicant has canceled claims 47-66 of copending Application No. 09/432,465.

Applicant's intent to file a terminal disclaimer is noted.

The new set of formal drawings were approved by the draftsman.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Friday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 38-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 3080-1235.

August 28, 2001


REBECCA COOK
PRIMARY EXAMINER
GROUP 1200